

Notice of Allowability

Application No.

10/715,903

Examiner

Henry S. Hu

Applicant(s)

ANDERSSON ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2nd RCE/IDS (after allowance) of September 19, 2007.
2. ☒ The allowed claim(s) is/are 1-21, 28, 40, 41 and 43.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 9-19-2007
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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DETAILED ACTION

1. Applicants' 2nd RCE and its newly submitted IDS were both filed on **September 19, 2007**. The examiner has closely considered the one NPL article as cited in this IDS. **Claims 1-21, 28, 40-41 and 43** with two independent claims (**Claims 1 and 28**) are now pending. An action follows.

Allowable Subject Matter

2. Claims 1-21, 28, 40-41 and 43 are allowed.

3. The following is an examiner's statement of reasons for allowance: The above claims 1-21, 28, 40-41 and 43 are allowed over the closest references:

4. The limitation of parent **Claim 1** in present invention relates to *an antimicrobial ophthalmic lens comprising a metal salt and having a percent haze of less than 200% and exhibiting, in the presence of viable bacteria or other microbes, a reduction of said viable bacteria or other microbes of at least about 0.5 log.*

Other parent **Claim 28** relates to *two-stepwise method of producing an antimicrobial ophthalmic lens comprising a metal salt, wherein said lens exhibits, in the presence of viable*

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bacteria or other microbes, a reduction of said viable bacteria or other microbes of at least about 0.5 log.

See other limitations of dependent Claims 2-21, 40-41 and 43.

5. The previous two Notices of Allowance filed on March 2, 2007 and June 22, 2007 respectively as well as one Supplemental Notice of Allowance filed on August 15, 2007 are now incorporated here by reference. In a close examination on the prior art as mentioned on the newly submitted IDS filed on September 19, 2007 along with a further examination and search, the examiner has found the following prior art did not teach the claimed limitation:

Applicants have claimed now in each of two parent claims including Claim 1 (composition) and Claim 28 (process of making) an unexpected way of obtaining an antimicrobial ophthalmic lens exhibiting an advantage as, in the presence of viable bacteria or other microbes, a reduction of said viable bacteria or other microbes of at least about 0.5 log. The key point is that the lens comprises a metal salt and having a percent haze at less than 200%. It is noted parent Claim 28 is the process of making the same composition of Claim 1.

Based on the fact that each of parent **Claims 1 and 28** in this 2nd IDS/RCE carries exact the same scope as the two allowed on March 2, 2007 and June 22, 2007. The same rationale for allowance is thereby applied here accordingly.

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6. In a very close examination on pending 102 and/or 103 rejections, all involving references including **Rathore, Borowsky, Barry and McCabe**, alone or in combination, cannot stand now with current claim limitation as follows:

In view of the **first Declaration** written by Inventors Rathore and Anderson as well as the statement on page **10** at top section of Remarks, USPG-PUB 2004/0151755 A1 Rathore et al. with effective US filing date of December 21, 2000 and the same assignee thereby cannot be used as a prior art for 102(e) rejection according to MPEP.

7. In view of the **second Declaration** written by Inventors Vanderlaan as well as different results being obtained by repeating US 4,576,453 to Borowsky's procedure, such obtained lens from Borowsky indeed does not show a reduction of viable bacteria more than 0.5 log.

Although **Borowsky or Barry** may disclose the preparation of contact lens by adding some metal ion such as silver salt (AgX) or silver zeolite in the form as a solution into a hydrogel lens so that metal ion can be stayed within gel matrix and such a contact lens having silver ion may be for antimicrobial purpose. However, each reference is still **silent of two things as:** (A) the lens property having the percent haze at less than about 200%, and (B) a reduction of viable bacteria more than 0.5 log.

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8. As pointed out by Applicants on pages 11 and 12 of Remarks, Barry provides no motivation to replace zeolites with the claimed metal salt, while McCabe does not disclose or suggest incorporating metal salts into a contact lens.

After further search, it is noted that **no search report** is found for Applicants' **PCT/US2003/037409 (WO 2004/047879 A2)** and the priority paper **EP 1,754,494 A2**.

9. After closely examining the references cited in a total of **three** IDS' including **one** NPL article by **Nissen** et al. cited in new IDS as well as **twelve** US patents cited in earlier IDS of June 4, 2007 and twelve patents (US, JP and WO) cited in earlier IDS of July 24, 2007, the references **do** disclose the preparation of some silver salt-containing antimicrobial products. **The salt can be silver chloride, silver nitrate, silver perchlorate and the like, while Nissen requires silver coating layer to be kept in sodium chloride solution for several hours** (see Nissen at page 1, bottom section; page 3, top section). Only **US 2005/0013842 A1** (however, it can not be used as prior art reference since it carries a US effective filing date of July 16, 2003) has mentioned the issue of haze (see paragraph 0287). In a very close examination, there is a key issue not disclosed or suggested by remaining cited references. Said key issue is on making a metal salt-containing antimicrobial ophthalmic lens so as to carry a combination of two properties as: (A) exhibiting a reduction of said viable bacteria or other microbes of at least about 0.5 log, and (B) the lens has a percent haze at less than 200%.

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10. Additionally, the present invention has shown in examples along with some comparative examples for making such an antimicrobial ophthalmic lens (see pages 23-51 for **examples 1-33** (with control) along with its **Tables 1-8**). Therefore, all the above-mentioned references, in combination or alone, does not teach or fairly suggest the limitations of present invention. In summary, the above references (which are mentioned before) and all newly cited IDS references, in combination or alone, fails to teach or fairly suggest the limitations of present invention.

11. After further examination and search, the examiner found the following prior art did not teach the claimed limitation:

US 5,520,910 to Hashimoto et al. (or its equivalent **WO 95/02617 to Hashimoto et al.**) only discloses an antimicrobial contact lens can be made from (A) **a polymer obtained by homo- or copolymerizing a phosphonium salt type vinyl monomer**, and (B) **a large quantity of an antimicrobial agent or a potent antimicrobial agent** (abstract, line 1-7; column 2, line 35-37). However, **metal salt is not disclosed or suggested**. The claimed percent haze and the claimed reduction of viable bacteria or other microbes are both not disclosed at all. Therefore, Hashimoto fails to teach or fairly suggest the copolymers of present invention.

US 6,815,074 B2 to Aguado et al. only discloses an ophthalmic antimicrobial contact lens useful for extended-wear periods can be made from (A) **a polymer obtained by polymerization of aoxypem macromer and an ionopem monomer** (abstract, line 1-10;

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column 2, line 35-37). Although lens haze is discussed (column 20, line 22-62), **metal salt is not disclosed or suggested adding into the lens composition**. The claimed percent haze and the claimed reduction of viable bacteria or other microbes are both not disclosed at all. Therefore, Aguado fails to teach or fairly suggest the copolymers of present invention.

12. The key issue on making a metal salt-containing antimicrobial ophthalmic lens so as to carry a combination of two properties as: (A) exhibiting a reduction of said viable bacteria or other microbes of at least about 0.5 log, and (B) the lens has a percent haze at less than 200%, cannot be overcome by any or the combination of the above references, therefore, the present invention is novel.

13. As of the date of this office action, the examiner has not located or identified any reference that can be used singularly or in combination with another reference including the above references to render the present invention anticipated or obvious to one of the ordinary skill in the art. Therefore, the two independent and parent **Claims 1 and 28** are allowed for the reason listed above. Since the prior art of record fails to teach the present invention, the remaining pending dependent **Claims 2-21, 40-41 and 43** are passed to issue.

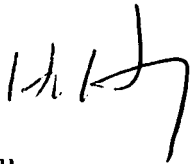
14. Any inquiry concerning this communication or earlier communication from the examiner should be directed to **Dr. Henry S. Hu** whose telephone number is **(571) 272-1103**. The examiner can be reached on Monday through Friday from 9:00 AM – 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The **fax** number for the organization where this application or proceeding is assigned is **(571) 273-8300** for all regular communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Peter D. Mulcahy/
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Primary Examiner
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Henry S. Hu

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December 10, 2007